K993969

DEC 30 1999

Rev01, 12-99

Section 15
510K Summary
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Submitter:	Winchester Laboratories LL Mr. Howard Rose President and CEO
Address	325 North Water Street Batavia, IL 60510
Telephone	630-406-8680
Contact Person.	Philip Totton Authorized Regulatory Agent 210 Silver Creek Road Greer, South Carolina 29650 Telephone: 864-292-0756 Fax: 864-244-9049
Date Prepared:	November 19, 1999
Trade Name.	Saljet Single Dose Sterile Saline Topical Solution, 0.9% w/v Sodium Chloride
Common Name:	Normal Saline Topical Solution, 0.9% w/v Sodium Chloride
Classification Name	Solution, Wound Dressing
Predicate Device:	Steripak Limited 20 ml. Normal Saline Topical Solution 0.9% w/v Sodium Chloride
Description	30-mL polyethylene vial containing Saline Topical Solution, 0.9% w/v Sodium Chloride Solution. Single-use.
Indications for Use	For use in moistening and lubricating absorbent wound dressings for traumatic wounds, cuts, bruises and minor burns prior to removal from the wound area.
Substantial Equivalence.	The product is similar in function and intended use to Steripak 20 mL Normal Saline Topical Solution manufactured by Steripak Limited and includes among it's labeled uses for moistening and lubricating absorbent wound dressing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 30 1999

Mr. Howard Rose
President and Chief Executive Officer
Winchester Laboratories, LLC
325 North Water Street
Batavia, Illinois 60510

Re: K993969
Trade Name: Saljet Single Dose Sterile Saline Topical Solution
Regulatory Class: Unclassified
Product Code: MUG
Dated: November 19, 1999
Received: November 23, 1999

Dear Mr. Rose:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Russell Payne

for James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Section 3
Intended Use of Device
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Device Name: Saljet Single Dose Sterile Saline Topical Solution
0.9% w/v Sodium Chloride

Indications for Use: For use in moistening and lubricating absorbent wound dressings for traumatic wounds, cuts, bruises and minor burns prior to removal from the wound area.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over – the – Counter Use ____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993969